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'Ethically Problematic': Pfizer Failed to Tell Pregnant Women in RSV Vaccine Trial About Preterm Birth Risk

According to an investigation by The BMJ, when GlaxoSmithKline Biologicals halted its RSV vaccine trial over preterm birth risks, Pfizer continued its similar trial while omitting these risks from consent forms. Experts criticized Pfizer's lack of transparency as an ethical violation compromising informed consent.

By **John-Michael Dumais**

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When Pfizer conducted a large clinical trial to test a new respiratory syncytial virus (RSV) vaccine for pregnant women — aimed at protecting their babies — the pharmaceutical giant failed to inform trial participants that GlaxoSmithKline Biologicals (GSK) had halted its trial for a similar vaccine due to a concerning safety signal showing a potential risk of preterm birth.

Even though Pfizer knew about the GSK trial and safety signal, it continued enrolling thousands of unsuspecting pregnant women without disclosing the preterm birth risk in its consent forms, according to an investigation by The BMJ.

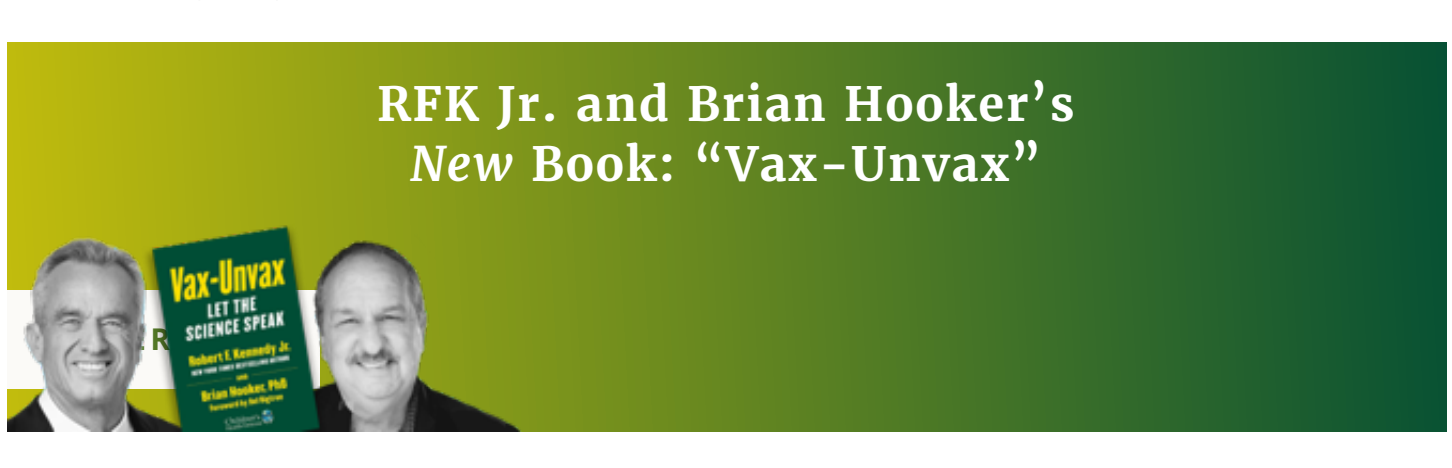
To many healthcare advocates and experts, Pfizer's omission represents an egregious violation of informed consent and a disregard for the autonomy of pregnant women participating in clinical research.

"Any failure to provide new and potentially important safety information data to trial participants is ethically problematic," Dr. Charles Weijer, bioethics professor at Western University in London, Ontario, Canada, told The BMJ.

Children's Health Defense CEO Mary Holland told The Defender:

> "I am horrified that it's even a question whether Pfizer should have told pregnant women that a previous clinical trial was halted because the RSV vaccine caused preterm birth. Of course it should have told them.
>
> "The standard must be, 'What would a reasonable pregnant woman want to know about this product?' And any reasonable pregnant woman would want to know if it causes preterm birth. This cavalier attitude towards the truth and human life is alarming."

After the safety signals emerged in GSK's study, the U.S. Food and Drug Administration (FDA) took no action to halt enrollment or to pause or restrict Pfizer's ongoing maternal RSV vaccine trial.


RFK Jr. and Brian Hooker's *New* Book: "Vax-Unvax"

'Statistically significant' shouldn't form sole basis of Pfizer's decision

Months after GSK's revelation of the concerning safety signal, Pfizer also began detecting a numerical imbalance in preterm births in its own trial data but said the data were not statistically significant.

According to The BMJ, Pfizer was tracking preterm births as an "adverse event of special interest" in its trial. But the company did not disclose this on consent forms given to thousands of pregnant trial participants across 18 countries.

"Once the results of the GSK trial on premature births became public, RSV vaccine studies in pregnant women should have been updated to include this possible preterm risk," said Klaus Überla, Ph.D., chair of Clinical and Molecular Virology at the University Hospital Erlangen, in The BMJ report.

However, regulators took little action to encourage disclosure. The FDA ultimately limited approval of Pfizer's vaccine to late pregnancy — specifically, for administration between 32-36 weeks only — due to preterm concerns. But the agency did nothing to restrict trial enrollment or require risk disclosure after the GSK findings emerged.

Some defend Pfizer's lack of disclosure to trial participants by arguing the preterm risk was inconclusive. Dr. Joop van Gerven, an ethics chair in the Netherlands, told The BMJ that informing women "would have caused too much uncertainty."

However, others challenged this notion. "The renewal of informed consent is a must," Rose Bernabe, Ph.D., told The BMJ.

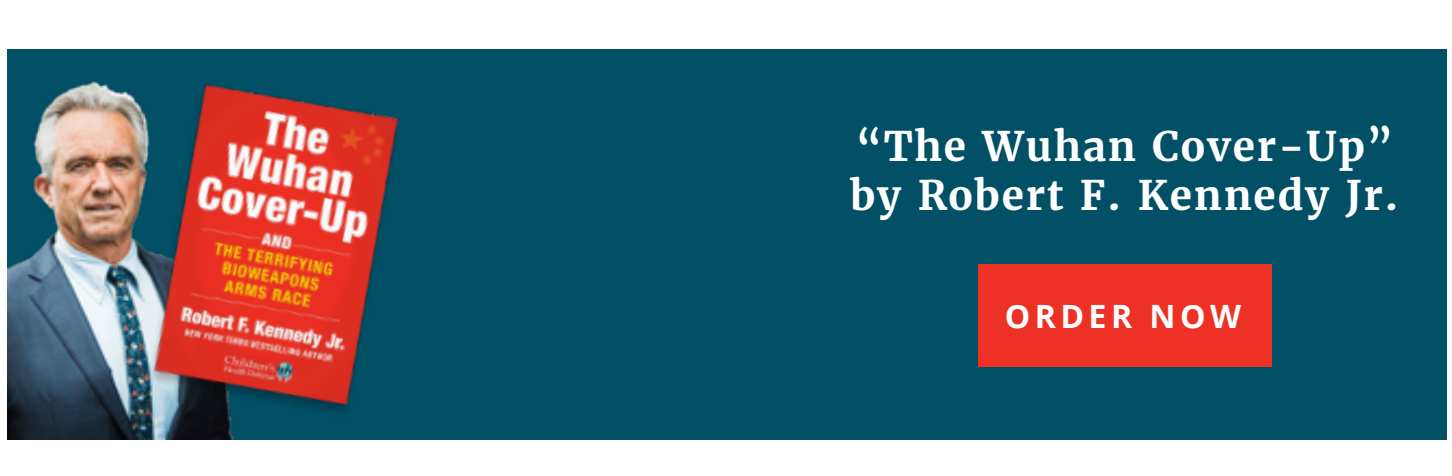
Bernabe, a professor of medical research ethics at the University of South-Eastern Norway, referenced guidelines from the Council for International Organizations of Medical Sciences, which state: "Researchers must renew the informed consent … if new information becomes available that could affect the willingness of participants to continue."

Weijer told The BMJ:

> "For Pfizer, the DSMB [Data Safety and Monitoring Board] should have regularly assessed the benefit-harm balance, both on the data in the trial and whether the GSK results affected that balance. They should not base their decision simply on whether a particular result is 'statistically significant.' These are difficult decisions, and it is why DSMBs are independent of the company."

Justine Tanguay, CHD lawyer and director of campaign research for Reform Pharma, told The Defender:

> "It's no surprise that regulatory agencies such as the FDA are prioritizing Big Pharma's profit over the health interests of its pregnant trial participants when you pull back the curtain and expose the revolving door between government's top federal employees and key executives for Big Pharma — the industry that FDA is supposed to be regulating.
>
> "In fact, the revolving door has become so commonplace that it is hard to decipher the tangled mess between the private sector and governmental agencies.
>
> "For instance, a former deputy director at the FDA who ran the Office of Vaccines Research and Review and pushed for the licensure of COVID-19 vaccines now works for Moderna as the head of the Infectious Diseases Early Clinical Development and Translational Medicine Program.
>
> "For the sake of public health, such egregious conflict of interests must end."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Robert F. Kennedy Jr.

'I think it needs to be addressed'

According to The BMJ investigation, in February 2022, GSK reported that a safety signal had emerged in its maternal RSV vaccine trial, indicating a concerning imbalance in preterm births between the vaccine and placebo groups.

Specifically, GSK observed that 6.81% of births in the vaccine arm were preterm, compared to just 4.95% of births in the placebo arm. Additionally, neonatal deaths were 0.37% in the vaccine group versus 0.17% in the placebo group.

This unexpected safety signal prompted GSK to immediately halt its Phase 3 trial and discontinue the development of its vaccine.

However, Pfizer's trial of a similar maternal RSV vaccine continued enrolling participants.

Both companies were developing versions of an RSV F protein vaccine that works by targeting the RSV fusion protein to generate antibodies that can neutralize the virus. The F protein is essential for viral entry and its structure is highly consistent across different strains of RSV.

In Pfizer's Phase 3 data, 5.7% of births in the vaccine arm were preterm compared to just 4.7% in placebo. Ten stillbirths occurred in the vaccine group versus eight in the placebo group. Neonatal deaths in the placebo group (.3%) exceeded those in the vaccine group (.1%). One vaccine recipient died from postpartum hemorrhage and hypovolemic shock.

Pfizer reported the increase in preterm births was most pronounced in trial participants from upper-middle-income countries, notably South Africa, according to the May 18 meeting of the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC).

While Pfizer claimed these numbers were not statistically significant, experts noted this numerical increase in preterm births mirrored the safety signal in the halted GSK trial, raising further questions about the risks of maternal RSV vaccination.

VRBPAC Chairwoman Hana El Sahly, during the May meeting, characterized the signal of increased preterm births during Pfizer's Phase 2 and 3 trials as "significant" and said it was "probably" reason enough to pause the trial. She said that "failing to design the Pfizer Phase 3 study to deliver that clarity … is a big missed opportunity."

Four of the 14 VRBPAC members were sufficiently concerned that they voted against finding the drug safe for pregnant women. Notably, one of the dissenting votes came from Dr. Paul Offit, a pediatrician at Children's Hospital of Philadelphia, who said, "If GSK truly abandons a program on a similar, almost identical vaccine, that is going to hang over [Pfizer's] program. I think it needs to be addressed."

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Vaccine efficacy inconclusive, limited, with 'no direct benefit to the mothers'

Peter McCullough, M.D., MPH, in an April 21 Substack post, raised a different point about the viability of the Pfizer vaccine, arguing Pfizer's study design relied on an outcome that occurred too rarely to reliably measure efficacy.

Basing results on fewer than 2% of babies getting sick left the findings "a statistical blur," he said — meaning the findings on whether the vaccine provided meaningful protection were inconclusive.

"Pfizer has aggressively advanced RCTs [randomized control trials] into the pregnant population with no assurances on long-term outcomes," McCullough added, and with "no direct benefit to the mothers."

In the May VRBPAC meeting, it was further noted that while the incidence of RSV for babies was lower in the vaccine group up to 6 months of age, during the 181- to 360-day period after birth, babies in both groups contracted RSV at similar rates.

After the Centers for Disease Control and Prevention (CDC) recommended the vaccine for pregnant women in September, McCullough told The Defender, "Vaccination of the mother for passive immunization of the infant is an unnecessary and risky strategy that will undoubtedly lead to fetal loss or premature deliveries when deployed on a large scale."

This controversy comes at a time when the CDC is reporting the largest rise in infant mortality in 20 years, and amidst concerns that doctors are being paid to push vaccines on pregnant women.

Warnings fell on deaf ears

The recent BMJ investigation was not its first warning about the RSV trials. On May 10, following Pfizer's publication of its Phase 3 trials data, The BMJ warned that Pfizer's safety signals were similar enough to GSK's to warrant further analysis.

Überla told The BMJ, "My interpretation of all these data is that there may be a safety signal for preterm births that should be followed up."

A scientist at the National Institutes of Health who wished to remain anonymous told The BMJ the Pfizer data should be analyzed using more sensitive measures such as average birth weight and subgroup analyses to determine the validity of the safety signal.

On May 23, The BMJ reported on the safety concerns noted by several VRBPAC members at their May meeting.

Before the FDA discussed the Pfizer RSV vaccine in May, "Peter Selley" from the U.K. posted a public comment to its website that said:

> "It is remarkable that the FDA:
>
> 1. Do not have an obstetrician or midwife on this VRBPAC committee.
> 2. Allowed these trials when, it seems, there were no safety trials of this vaccine in pregnant non-human primates.
> 3. Allowed these large trials in pregnant women when pregnant women had been specifically excluded from smaller Phase 1 safety trials.
> 4. Allowed Pfizer's phase 2 trial that involved 3-5 venous blood draws from healthy babies who would derive no benefit.
> 5. When notified in February 2022 by GSK of a safety signal of excess preterm births and neonatal deaths in a trial of a similar RSV vaccine, the FDA did not insist that participants in Pfizer's Phase 3 trial should be informed of the finding.
> 6. Authorized an Institutional Review Board – Advarra – that approved the Phase 3 trial in pregnant women. Advarra's informed consent form for the ongoing trial contains the advice: "The risks associated with the study vaccine (RSVpreF or placebo) may be experienced by you, but not your baby, since your baby will not receive the study vaccine or placebo directly." (According to the trial protocol, this wording was also approved by Pfizer.)
> 7. Allowed the Phase 3 trial to stop early, although this may have prevented participants from experiencing adverse reactions."

Selley appended a document detailing further safety considerations in the Pfizer trials, where he also cited Dr. Eric Simões, lead author of the Phase 2 study, who wrote in a different study, "The role of breast-feeding in preventing RSV disease and hospitalization for RSV is undisputed."

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John-Michael Dumais
John-Michael Dumais is a news editor for The Defender. He has been a writer and community organizer on a variety of issues, including the death penalty, war, health freedom and all things related to the COVID-19 pandemic.

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tag
14 days ago
How convenient. Allowed to murder with no accountability.
9 0 Reply • Share ›

janis moss
14 days ago
What is the matter with physicians??? Nothing should be given to pregnant women in the form of drugs or vaccinations! The fetus is growing so fast, any chemical given to the mother could cause a disruption in the development of the fetus. Mothers should be encouraged to eat clean, organic foods and stay away from any chemicals, fumes or drugs. It used to be okay to take tylenol, and now even that is suspect. Use your brains, people. Take care of those precious babies.
9 0 Reply • Share ›

Michael → janis moss
13 days ago
What is wrong with physicians?
Big pharma pays them to administer their drugs.
Big pharma pays medical schools to teach their drugs.
Big pharma pays FDA, CDC and NIH to approve their drugs.
10 0 Reply • Share ›

anotheroldvet → Michael
12 days ago
Bullseye!
Give that man a cigar and a double shot of his choice off the top shelf.
4 0 Reply • Share ›

Alex Smith → Michael
11 days ago edited
That is correct. Very useful information contained in the book Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Healthcare by Peter Gotzsche.
0 0 Reply • Share ›

Kim from Brooklyn → janis moss
13 days ago edited
And just to add to your comment: 'nothing should be given to pregnant women that is in the EXPERIMENTAL phase.

Kind of asinine that they shame women who smoke and drink during pregnancy as abusive yet it's acceptable? to bombard women with an experimental, now evidence shows VERY DEADLY ? bioweapon!!

Just goes to show the brainwashing we must endure daily. :(
8 0 Reply • Share ›

Alex Smith → janis moss
11 days ago
What is wrong with physicians? Have you read the Treaty of Versailles of 1919? Clearly its outlined objective was to officially impose the causal factors of WW II. Creating the Nazis was the main goal of the evil FBI *directorate* since day 1 back in 1907, and now those two outfits are fascist, sadistic lovers. The Nazis and the *directorate* of the CIA, FBI, Pentagon & NSA are now one big, fascist sadistic family running the industrialized medical-military mafia.
0 0 Reply • Share ›

unacceptable views → janis moss
11 days ago
What's wrong with the mothers? They weren't forced into this, they have brains and the ability to do some educating but they chose to be lab rats for Big Pharma when they have tons of info out there that screams why they shouldn't choose this. Personal accountability has a place here, the individual must be responsible for their own actions as well as Big Pharma and the physicians.
0 0 Reply • Share ›

Frederick Lee
13 days ago
To clear up the issues surrounding informed consent, why not limit "medical studies" to Big pharma executives, company researchers, the WHO, FDA, CDC, NHA, etc., board members and voting members, and their researchers, and any and all family members of any of these individuals. I dont know how many of them are pregnant, planning to become pregnant, not planinng to become pregnant but become pregnant anyway, etc., but once the "authority" says the "study" is approved, bingo, you are enrolled. This large pool of "volunteers" (even though employment is conditioned on participation) should be enough to generate "statistically significant" results.
In this scenario, no matter how the researcher or family member or CDC executive voted, they will be part of the non-placebo group. I am confident that medical issues will be thoroughly analyzed.
The placebo group will be limited to the youngest, most athletic, healthiest people, pregnant, non-pregnant, whoever. No informed consent is needed, because, its a placebo, so all who are healthy are welcome. Smokers, chewers, THC users, illegal and legal drug users, etc will be excluded from the placebo group, but not excluded from the test group. But to be in the test group, you must be a member or a family member of the "healthcare" research entity.
The expected outcome is that the non-placebo group should become as healthy as the placebo group, and any disparaties after adjusting for age, etc, can be researched. Birth defects may not show up immediately, but dont worry, the parents already provided informed consent, so when you grow up, you can thank them then.
6 0 Reply • Share ›

Ektor
13 days ago
Fizer hides the truth with every drug they market. What a terrible company that never should be allowed to murder humans as they do.
4 0 Reply • Share ›

unacceptable views → Ektor
11 days ago
And many humans line up to be murdered by Big Pharma. I don't. Why? Because I choose to ask questions. If you choose to not ask questions, what happens is on you.
0 0 Reply • Share ›

Thomas Cordery → unacceptable views
9 days ago
Abuse of the naive, the gullible, the foolish and the uninformed is always on the abuser. That's particularly so where a culture of trust exists, or where the abuser is in a position of power, authority, or has relevant information that they take steps to keep from the abused.
0 0 Reply • Share ›

Rob DF
13 days ago
Just Pfizer being Pfizer.
2 0 Reply • Share ›

Thomas Cordery → Rob DF
9 days ago
Pfizer gotta pfize.
1 0 Reply • Share ›

Jennifo
13 days ago
We've lost our damn minds. ANY preterm death is horrendous. To use any of it to get to a statistic is morbid. How can mothers be so stupid? If you shouldn't drink or smoke while pregnant, why in the world would you put a foreign substance in? Honestly shaking my head.
2 0 Reply • Share ›

MultiChubby1 → Jennifo
13 days ago
"ANY preterm death is horrendous" Does that include abortion?
1 0 Reply • Share ›

Jennifo → MultiChubby1
12 days ago
Whats your point to me? We're talking giving shots to pregnant women, I'm not going to argue an entirely other topic.
0 0 Reply • Share ›

MultiChubby1 → Jennifo
12 days ago
Just pointing out the obvious hypocrisy. In one room doctors are frantically attempting to resuscitate a 34 week old preterm infant and in another room they are pulling the same from the uterus down the birth canal far enough to sever the baby's spinal cord at the base of it's brain in order to deliver it dead.

Have a nice day.
0 0 Reply • Share ›

Jennifo → MultiChubby1
12 days ago
Ah. Yeah. It's all so disturbing.
0 0 Reply • Share ›

Geduldete
13 days ago
It seems to make a difference if the study is made bei Pfizer or by another Pharmacompany.
1 0 Reply • Share ›

MultiChubby1
13 days ago
This cavalier attitude towards the truth and human life is alarming." lol
1 0 Reply • Share ›

Alex Smith
11 days ago edited
Pfizer illegally hid and omitted fatal supernumerary lumbar rib birth defects as a side effect exhibited by their test subjects during the COVID vaccine bio torture trials. That revelation required a FOIA to uncover it. That means Pfizer is guilty of fraud. Having committed a cover up, they are to be stripped of their legal immunity originally granted under the FDA's emergency use authorization (EUA.)

One can read the article by The Expose titled FOIA reveals Pfizer & Medicine Regulators hid dangers of COVID Vaccination during Pregnancy after Study found it increases risk of Birth Defects & Infertility.

To make matters more **incriminating** for both the corrupt-as-sin FDA and Pfizer, the FDA actually granted Pfizer's COMIRNITY vaccine FULL approval. It was the fatal "COMIRNATY" Pfizer COVID vaccine that actually was reported to cause fatal supernumerary lumbar rib birth defects! Pfizer stated that COMIRNATY is nearly identical to the experimental BNT162b2 COVID vaccine, both in its ingredients and formulation.
0 0 Reply • Share ›

Gary Brown
11 days ago
APRIL 14. 2023 Doubled Pregnancy Loss Rate, Raised Foetal Abnormality Rate and Concentration of Lipid Nanoparticles in Ovaries – How Could They Call This Vaccine 'Safe'?

Recently, a lengthy vaccine evaluation reportsponsored by Pfizer and submitted to the Australian regulator, the Therapeutic Goods Administration (TGA) dated January 2021 was released under a Freedom of Information request. The report contains significant new

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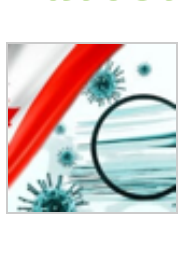

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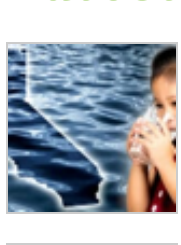

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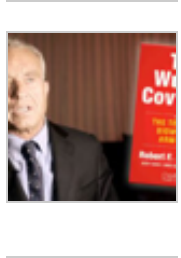

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